

REMARKS

Claims 1-26, 28-31, 33-40, 42, 44, and 45 are pending in this application. With this reply, Applicants have amended claims 1-20, 24, 25, 28-31, 33, 34, 38, 39, 42, and 44 to more clearly point out the claimed subject matter. Applicants have also added new claims 48 and 49. Support for these amendments may be found in the specification as filed at, e.g., paragraphs [0078] and [0082].

Claim Objection

The Examiner has objected to claim 11 for reciting the phrase “the amino acid corresponds” rather than “the amino acids correspond” (Office Action, page 2). Applicants have amended the claim according to the Examiner’s suggestion, rendering the objection moot.

Indefiniteness

The Examiner has rejected claims 12-18 and 20-24 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter Applicants regard as their invention. Specifically, the Examiner alleges that claims 12-18 and 20-24 are indefinite because

it is not clear **(1)** if the full-length BAFF-R glycoprotein of claim 1 already inherently comprises the amino acid sequences listed as (a)-(f), **(2)** if the full-length BAFF-R is further modified by the *addition or fusion* of the amino acid sequences listed as (a)-(f), or **(3)** if the extracellular domain of the full-length BAFF-R glycoprotein consists of the amino acids listed as (a)-(f).

Office Action of May 15, 2009, at 3 (original emphasis).

Without acquiescing to the rejection of the previously pending claims, Applicants submit that the amended claims are clear. “If the claims when read in light of the

specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.” PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1562–63, 37 U.S.P.Q.2d 1618 (Fed. Cir. 1996). The skilled artisan would readily understand the scope of claims 12-18 and 20-24. Claim 1, from which the claims at issue depend, relates to a glycoprotein comprising the extracellular domain of a non-naturally occurring BAFF-R, wherein the extracellular domain has a deletion that results in an altered O-linked glycosylation pattern while retaining the ability to bind to BAFF. Dependent claims 12-18 provide that certain amino acid sequences must be present in the extracellular domain. Similarly, claim 19 relates to a nucleic acid encoding the glycoprotein of claim 1, and dependent claims 20-24 provide that the nucleic acid must encode certain amino acid sequences. Simply put, the claims at issue describe amino acid sequences that must be present in the BAFF-R after the deletion recited in claim 1.

In view of these remarks, Applicants submit that the claims clearly and distinctly point out the invention. Applicants respectfully request reconsideration and withdrawal of the indefiniteness rejection.

Enablement

The Examiner has rejected claims 38 and 42 as allegedly failing to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. The Examiner states that the specification does not enable the skilled artisan to make and use the full scope of the claimed invention.

Host cells

The Examiner acknowledges that the specification enables the skilled artisan to make and use the host cells recited in claim 38 if they are isolated. The Examiner has

interpreted claim 38, however, as “read[ing] upon host cells intended for gene therapy.” Office Action of May 15, 2009, at 4. The Examiner contends that host cells intended for gene therapy are not enabled.

Without acquiescing to the Examiner’s rejection and solely in the interests of advancing prosecution, Applicants have amended claim 38 to recite an “isolated host cell.” Applicants note for the record that amended claim 38 is not limited to any particular use of the isolated host cells. Rather, this claim is intended to encompass any isolated host cell as recited, regardless of intended use. Thus, while Applicants maintain that the specification enables therapeutic uses of the claimed host cells, that is not required for claim 38 to be enabled. When the claim in question is drawn to a composition, without limitation to any particular use, the first paragraph of 35 U.S.C. § 112 only requires the specification to enable a single use. See M.P.E.P. § 2164.01(c) (“if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention.”). As acknowledged in the previous Office Action, the specification enables at least the use of isolated host cells to produce BAFF-R glycoprotein, e.g., as described in claim 24. Thus, claim 38 is enabled.

Method for treating an immunological disorder

The Examiner has rejected claim 42 for reciting a “method for treating an immunological disorder.” The Examiner acknowledges that the specification enables a method for treating an autoimmune disorder characterized by an elevated BAFF level. The Examiner asserts, however, that “undue experimentation would be required of the skilled artisan to administer the BAFF-R glycoprotein to individuals with all possible immunological disorders.” Office Action of May 15, 2009, at 3-7.

Without acquiescing to the Examiner's rejection and solely in the interests of advancing prosecution, Applicants have amended claim 42 to recite a "method for treating an autoimmune disease characterized by an elevated BAFF level." As noted above, the Office Action acknowledges that the specification enables the amended claim.

Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 38 and 42 for lack of enablement.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and timely allowance of the claims. Applicants invite the Examiner to call the undersigned Applicants' representative with any questions or comments.

Please grant any extensions of time required to enter this response and charge any additional required fees to deposit account 06-0916.

Respectfully submitted,

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